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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

Food and Drug Administration

[Docket No. 03D–0063]

# Medical Devices: Guidance for Industry and FDA: Fiscal Year 2003 Medical Device User Fee and Modernization Act of 2002 Small Business Qualification Worksheet and Certification; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "FY 2003 MDUFMA Small Business Qualification Worksheet and Certification." This guidance explains how you can certify that you qualify as a "small business" within the meaning of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and provides a copy of, and instructions for, Form FDA 3602, "FY 2003 MDUFMA Small Business Qualification Certification." If FDA decides that you are a small business, you will be eligible for reduced or waived small business fees for medical device applications that you submit from October 1, 2002, through September 30, 2003.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "FY 2003 MDUFMA Small Business Qualification Worksheet and Certification" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and

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Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Thomas E. Cardamone, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–0806, ext. 117.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is providing guidance on how you may qualify as a "small business" within the meaning of MDUFMA. MDUFMA requires FDA to collect a user fee from each person who submits certain medical device applications for FDA review. MDUFMA user fees range from $2,187 to $154,000, depending on the type of application. The fees for fiscal year (FY) 2003 are summarized in table 1 of this document. A "small business" is eligible for reduced or waived fees.

To qualify as a small business, your "gross receipts or sales," including that of all of your affiliates, partners, and parent firms, cannot exceed $30 million. See section 738(d)(2)(A)(i) and (e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379j(d)(2)(A)(i) and (e)(2)(A)). When you submit an application that is subject to a MDUFMA user fee, you must pay

the standard fee unless you have provided information to FDA that demonstrates that you are a small business.

TABLE 1.—FY 2003 MEDICAL DEVICE REVIEW USER FEES[1]

| Application | Standard Fee | Small Business |
|---|---|---|
| Premarket application (PMA[1], PDP[1], BLA[1]) | $154,000 | $58,520 |
| Premarket report (premarket application for a reprocessed single-use device) | $154,000 | $58,520 |
| First premarket application by a small business | Not applicable | Fee is waived |
| Panel-track supplement | $154,000 | $58,520 |
| Efficacy supplement | $154,000 | $58,520 |
| 180-day supplement | $33,100 | $12,582 |
| Real-time supplement | $11,088 | $4,213 |
| 510(k) | $2,187 | $2,187[2] |

[1]PMA means premarket approval applications, PDP means product development protocol, and BLA means biologics license application
[2]During FY 2003, all 510(k) applicants will pay the standard fee. A reduced small business fee will be available beginning FY 2004.

FDA is making this guidance effective immediately because there is a statutory requirement that requires immediate implementation and guidance is needed to help effect such implementation. As soon as Congress enacts an appropriation authorizing FDA to collect and spend MDUFMA user fees, we will begin to collect those fees. You must pay the full standard fee unless you demonstrate you are a small business (section 738(d)(2)(B) and (e)(2)(B) of the act). You will pay a fee for each application you submit on or after October 1, 2002, if that application is subject to a fee. If you do not pay a fee when MDUFMA requires you to do so, FDA will not file or review your application.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on small entities and MDUFMA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

You may obtain a copy of "FY 2003 MDUFMA Small Business Qualification Worksheet and Certification" via your fax machine by calling the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to enter the system. At the second voice prompt press 1 to order a document, then enter the document number (1204) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

You may also obtain a copy of the guidance through the Internet. FDA provides this guidance and additional information on MDUFMA at http:// www.fda.gov/oc/mdufma. FDA periodically updates this site to provide you the most current information and guidance concerning the MDUFMA program.

## IV. Paperwork Reduction Act

This draft guidance contains a collection of information that requires clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

## V. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. Electronic comments may be submitted at http://www.fda.gov/dockets/ecomments. The guidance

document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 3/12/03
March 12, 2003.

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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